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APPEAL BRIEF

This Appeal Brief is filed in support of Appellant's appeal from the decision of the Examiner dated June, 7, 2006, rejecting all pending claims.

I. REAL PARTY IN INTEREST

The subject application is owned by Flight Health, Inc., of Charlestown, Massachusetts.

II. RELATED APPEALS AND INTERFERENCES

To the best of Appellant's knowledge, no other appeals or interferences are pending which will directly affect, or be directly affected by, or have a bearing on, the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 1-20 are being appealed.

Claims 1-20 are pending in the subject application.

Claims 1-20 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Claims 1-20 also stand rejected under 35 U.S.C. § 103(a) as being unpatentable over both Jones et al., *American Journal of Emergency Medicine* ("*Jones*"), and Singletary et al., *American Journal of Emergency Medicine* ("*Singletary*").

IV. STATUS OF AMENDMENTS

No amendments have been filed subsequent to the final rejection.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The invention of independent claim 1 is a method of relieving the potential for symptoms of ear and sinus cavity blockage in a descending aircraft (*see* page 4, lines 6-18; and page 5, lines 8-9). The method of claim 1 includes ingesting a nasal decongestant at least one hour before the scheduled aircraft landing time, for non-specific shrinking of the nasal lining (*see* page 5, lines 9-11, and lines 20-21; page 5, line 22 – page 6, line 1; and page 6, lines 16-18); and applying a nasal decongestant spray into the nose later in flight than the ingestion of the nasal decongestant,

to shrink the nasal lining (*see* page 5, lines 12-13; and page 6, lines 7-12, and lines 14-15). In the method of claim 1, the ingested and sprayed decongestants help to shrink the mucosa, including at least the nasal lining, to decrease the pain associated with blockage as an aircraft descends (*see* page 5, lines 8-9, and lines 20-21; and page 6, lines 8-10, and lines 12-18).

Claims 2 – 9 are dependent upon claim 1.

The invention of independent claim 10 is a method of relieving the potential for symptoms of ear and sinus cavity blockage in a descending aircraft (*see* page 4, lines 19-24; and page 5, lines 8-9). The method of claim 10 includes ingesting about 60 mg of pseudoephedrine at least one hour before the scheduled aircraft landing time, for non-specific shrinking of the nasal lining (*see* page 5, lines 9-11; page 5, line 20 – page 6, line 3; and page 6, lines 16-22, and lines 19-22); and applying a nasal decongestant spray into the nose after the pseudoephedrine ingestion and within about one hour of scheduled landing time, to shrink the nasal lining (*see* page 5, lines 12-13; and page 6, lines 7-12, and lines 14-15). In the method of claim 10, the ingested and sprayed decongestants help to shrink the mucosa, including at least the nasal lining, to decrease the pain associated with blockage as an aircraft descends (*see* page 5, lines 8-9, and lines 20-21; and page 6, lines 8-10, and lines 12-18).

Claims 11 and 12 are dependent upon claim 10.

The invention of independent claim 13 is a kit for use in relieving the potential for symptoms of ear and sinus cavity blockage in descending aircraft (*see* page 5, lines 1-6, and lines 8-9). The kit includes a first medication comprising an oral nasal decongestant (*see* page 5, lines 9-11, line 13, lines 15-18, and lines 20-22); and a second medication comprising a nasal spray decongestant (*see* page 5, lines 12-13, and lines 15-18; and page 6, lines 7-12, and lines 14-15).

The kit of claim 13 also includes instructions for the user to ingest a proper dose of the oral nasal decongestant at least one hour before the scheduled aircraft landing time (*see* page 5, lines 13-18; and page 7, lines 6-7) and to subsequently spray the nasal spray decongestant into at least one nostril within about one hour of the scheduled landing time (*see* page 5, lines 13-18; and page 7, lines 6-7). In the kit of claim 13, the ingested and sprayed decongestants help to shrink at least the nasal lining, to decrease pain associated with blockage as the aircraft descends (*see* page 5, lines 8-9 and lines 20-21; page 6, lines 2-4 and lines 12-18).

Claims 14 – 20 are dependent upon claim 13.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether claims 1-20 are unpatentable under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement; and

2. Whether claims 1-20 are unpatentable under 35 U.S.C. § 103(a) over both Jones et al., *American Journal of Emergency Medicine* ("*Jones*"), and Singletary et al., *American Journal of Emergency Medicine* ("*Singletary*").

VII. ARGUMENT

1. FIRST GROUND OF REJECTION:

Claims 1-20 were rejected as unpatentable under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

The Examiner rejected claims 1-20 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner stated "[c]laims 1[, 10] and 13 have been amended to recite 'relieving the potential for' symptoms of ear and sinus cavity blockage....The specification does not describe and does not support the amendment to claims 1[, 10] and 13 drawn to 'relieving the potential for' symptoms of ear and sinus cavity blockage." *June 7, 2006 Office Action*, at page 2, paragraphs 3 and 4. The Examiner is referring to amendments made by the Appellant on March 22, 2006, in response to the September 23, 2005, Office Action.

The Applicant points to the following excerpts from the Specification in support of independent claims 1, 10 and 13:

"The oral medication and the spray medication act adjunctively and additively to *relieve the potential* for ear and sinus symptoms associated with descent. This is the rationale for combining both the pill and the spray." *Specification*, at page 6, lines 16-18 (emphasis added).

"The second (late in flight) medication is a topical nasal decongestant delivered as a nasal spray, typically one or two sprays in each nostril...The rationale for the spray is that it defuses congestion immediately and *obviates* the associated barometric otitis (ear pressure) and barometric sinus pressure." *Specification*, at page 6, lines 7-15 (emphasis added) ("obviate: to anticipate and prevent (as a situation) or make unnecessary (as an action)," *Webster's Ninth New*

Collegiate Dictionary, at page 816.

"Blockage of the ears occurs when the pressurization of the aircraft drops below eight thousand feet, which usually occurs within about an hour of landing in commercial aircraft. This is the time at which appropriate *preemptive treatments* will be useful in *obviating* barometric-induced symptoms of ear blockage, which can range from just blockage to severe pain and actual hemorrhage or rupture of the eardrum. The same barometric scenario which produces blocked ears, also accounts for blocked sinuses and associated pain." *Specification*, at page 3, line 19 – page 4, line 2 (emphasis added).

Clearly, then, these passages from the Specification describe and support claims 1, 10 and 13, and these claims are patentable under 35 U.S.C. § 112, first paragraph. As claims 2-9, 11-12, and 14-20 are dependent upon claims 1, 10, and 13, respectively, these dependent claims are also supported by the Specification and are patentable under 35 U.S.C. § 112, first paragraph.

2. SECOND GROUND OF REJECTION:

Claims 1-20 were rejected as unpatentable under 35 U.S.C. § 103(a) over both Jones et al., *American Journal of Emergency Medicine* ("*Jones*"), and Singletary et al., *American Journal of Emergency Medicine* ("*Singletary*").

The Examiner rejected claims 1-20 under 35 U.S.C. § 103(a) as unpatentable over *Jones* and *Singletary*. Claims 1-20 are patentable over *Jones* and *Singletary* for at least three reasons. First, the Examiner's reasoning for combining the references is improper under the law of 35 U.S.C. § 103. Second, the cited references teach away from the claimed invention, and thus cannot be used to establish a *prima facie* case of obviousness. Third, even if *Jones* and *Singletary* are combined, the combined references do not disclose all the elements of claims 1-20.

A. The Examiner's reasoning for combining the references is improper under the law of 35 U.S.C. § 103.

In any obviousness determination, the patent examiner must determine the scope and content of the prior art, the differences between the prior art and the claims at issue, and the level of ordinary skill in the pertinent art, as established in *Graham v. John Deere Co.*, 383 U.S. 1, 148 U.S.P.Q. 459 (1966). Patentability turns on whether the subject matter as a whole sought to be patented was obvious to one with "ordinary skill in the art to which the subject matter pertains" in light of the prior art. *Id.* at 3. "In determining the differences between the prior art and the claims, the question under 35 U.S.C. § 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious." M.P.E.P. §2141.02, *citing*, *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 U.S.P.Q. 871 (Fed. Cir. 1983); *Schenck v. Nortron Corp.*, 713 F.2d 782, 218 U.S.P.Q. 698 (Fed. Cir. 1983) (emphasis in original).

Further, when making any obviousness determination, there must be a suggestion or motivation to modify a prior art reference. "'Determining whether there is a suggestion or motivation to modify a prior art reference is one aspect of determining the scope and content of the prior art, a fact question subsidiary to the ultimate conclusion of obviousness.'" *Ruiz v. A.B. Chance*, 57 U.S.P.Q.2d at 1167, *quoting*, *Sibia Neurosciences, Inc. v. Cadus Pharma. Corp.*, 225 F.3d 1349, 1356, 55 U.S.P.Q.2d 1927, 1931 (Fed. Cir. 2000). The suggestion, teaching or reason must come from the prior art itself; it cannot be based on hindsight in view of the claims. *McGinley v. Franklin Sports, Inc.*, 60 U.S.P.Q.2d 1001, 1008 (Fed. Cir. 2001), *citing, In re Dembiczak*, 175 F.3d 994, 999, 50 U.S.P.Q.2d 1769 (Fed. Cir. 1999) ("guarding against falling

victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher"). In addition, no suggestion or motivation for modifying a reference exists if such a modification would render the invention of the reference unsatisfactory for its intended purposes. *See In re Gordon*, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984).

In this case, the combination of *Jones* and *Singletary* is improper because there is no suggestion or motivation in the prior art to make such a combination. The Examiner has made the combination using impermissible hindsight, and the invention as a whole is not obvious.

The Examiner states that it would have been obvious to combine *Jones* and *Singletary* because "one skilled in the otolaryngology art would have been motivated to prepare a kit comprising both oral and aerosol decongestant products from among the very well established commercial products, phenylephrine, oxymetazoline and pseudoephedrine, that are known in the prior art for alleviating the symptoms of ear and sinus blockage. Since the time at which barotrauma occurs is on descent, and, since about an hour would be required to achieve effective absorption of the decongestant, nothing unobvious is noted in ingesting a nasal decongestant about an hour prior to landing." *June 7, 2006 Office Action*, at page 4, paragraph 2.

Here, claim 1 is directed to a method of relieving the potential for symptoms of *ear and sinus cavity blockage* by ingesting a nasal decongestant *and* applying a nasal decongestant spray into the nose. Claim 13 is similarly directed to a kit for use in relieving the potential for symptoms of *ear and sinus cavity blockage* with instructions to ingest the oral decongestant *and* spray the nasal decongestant into at least one nostril.

In contrast, *Jones* describes a study in which volunteers were given *either* an oral decongestant *or* a topical decongestant to prevent *middle ear barotrauma*. *Jones*, at 262. *Jones*

does not disclose or suggest combining the medications and taking both an oral and a topical decongestant. Nor does *Jones* disclose or suggest taking an oral decongestant for sinus cavity blockage, as noted by the Examiner. *September 23, 2005 Office Action*, at page 2, last paragraph ("Jones fails to discuss *sinus cavity blockage*.") (emphasis added).

Claim 1 is further directed to ingesting a nasal decongestant at least one hour before the scheduled aircraft landing time and applying a nasal decongestant spray into the nose *later in flight*. Similarly, claim 13 is further directed to instructions for ingesting a nasal decongestant at least one hour before the scheduled aircraft landing time and *subsequently* spraying the nasal decongestant within about one hour of the scheduled landing time.

In contrast, in *Jones*, the sole medication was "administered at least 30 minutes before flying," and the "[s]ubjects were instructed to *abstain* from taking any other decongestant or antihistamine medication (topical or oral) until the completion of their flight." *Jones*, at 262 (emphasis added). *Jones* does not disclose or suggest applying the nasal decongestant spray *after* the oral decongestant. Nor does *Jones* suggest that the nasal decongestant spray should be applied *during the flight.*

The second reference, *Singletary*, describes a case in which a patient was treated with both an oral decongestant and a topical decongestant *after* being seen in the emergency room for *acute sinus pain* during descent on a commercial airliner. *Singletary*, at 329. *Singletary* does not disclose or suggest taking both an oral and a topical decongestant to *prevent* symptoms of frontal sinus pain. The sole preventative measure discussed in *Singletary* is avoiding flying or diving "until all signs and symptoms have been resolved." *Singletary*, at 331. Further, there is no suggestion or motivation in *Singletary* to use the same treatment for the relief of *middle ear*

barotrauma.

In addition, modifying *Jones* such that each subject takes both an oral decongestant and a topical decongestant would destroy the intent, purpose and function of *Jones*, since the purpose of the *Jones* study was to compare the efficacy of the two decongestants. As such, there is no suggestion or motivation for modifying *Jones*, because it would render *Jones* "unsatisfactory for its intended purpose." *In re Gordon*, 733 F.2d at 902.

The Examiner's combination of *Jones* and *Singletary*, then, is made without any suggestion in the art to make such combination. In fact, the only suggestion for combining an oral and a nasal decongestant for relieving the potential for symptoms of ear and sinus cavity blockage, by ingesting a nasal decongestant at least one hour before the scheduled aircraft landing time and applying a nasal decongestant spray into the nose later in flight, comes from Applicant's Patent Application. Thus, without the impermissible reference to Applicant's disclosure, there is no motivation to combine *Jones* with *Singletary*, and the invention as a whole is not obvious.

B. The references teach away, and therefore cannot be used to establish a *prima facie* case of obviousness.

"[A]n applicant may rebut a *prima facie* case of obviousness by showing that the prior art teaches away from the claimed invention in any material respect." *In re Peterson*, 315 F.3d 1325, 1331 (Fed. Cir. 2003); *see also Gillette Co. v. S.C. Johnson & Son, Inc.*, 919 F.2d 720, 724 (invention not obvious where closest prior art reference "would likely *discourage* the art worker from attempting the substitution suggested...") (emphasis in original).

Here, *Jones* teaches away from the claimed invention. Specifically, *Jones* teaches away

from administering a topical nasal decongestant as a preventative measure. "These results are consistent with the controlled trial by Carson et al, which demonstrated that topical oxymetazoline was not effective in preventing middle ear barotrauma during hyperbaric oxygen therapy." *Jones*, at 264. In the conclusion, *Jones* states "[o]xymetazoline nasal spray was no more effective than placebo in reducing middle ear pain and discomfort associated with changing ambient pressures." *Jones*, at 264.

The Examiner has taken a similar statement from the *Jones* Abstract and misconstrued the implication. The Examiner stated, "[t]he recitation 'oxymetazoline nasal spray is little more effective than placebo' indicates that there was some efficacy in reducing ear and sinus blockage." *June 7, 2006 Office Action*, at page 3, third paragraph. Clearly, in the context of the entire reference, the authors of the *Jones* study are not endorsing or suggesting the use of topical nasal decongestants to prevent or reduce ear pain during travel. In fact, *Jones* specifically states, with reference to hyperbaric oxygen therapy, "[u]ntil further research is done in this area, the routine use of topical decongestants in these patients should be reconsidered." *Jones*, at 264.

The study referred to in *Jones*, Carson et al., is also referenced by Capes et al., *American Journal of Emergency Medicine*, ("*Capes*"), which was cited by the Examiner in the most recent office action. *June 7, 2006 Office Action*, at page 4. *Capes* is not directed to airline travel, nor does it suggest or disclose the claimed combination of medications to prevent or treat middle ear barotrauma associated with airline travel. In reference to Carson, et al., *Capes* states "[u]nfortunately, for preventing middle ear barotrauma, Carson et al showed topical decongestants, ie, oxymetazoline, to be *ineffective* in patients undergoing [hyperbaric oxygen treatment]." *Capes*, at 647 (emphasis added). Further, *Capes* questions the use of topical nasal

decongestants, saying "[t]his is contrary to existing research, which shows that only oral decongestants, and not topical, are effective in preventing otic barotrauma." *Capes*, at 647. *Capes*, therefore, teaches away from the claimed invention.

In addition, *Jones* teaches away from taking either an oral or topical medication *during the flight*. The study specifically required participants to "abstain from taking any other decongestant or antihistamine medication (topical or oral) until completion of their flight." *Jones*, at 262.

In summary, then, the references cited by the Examiner teach away from the invention, and thus cannot be used to establish a *prima facie* case of obviousness.

C. Even if combined, the references do not disclose all the elements of claims 1-20.

"To establish *prima facie* case of obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art." M.P.E.P. § 2143.03, *citing*, *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *Id.*, *citing*, *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (CCPA 1970).

The combination of Jones and Singleton does not disclose at least one element of the claimed invention, either directly or inherently.

At best, the combination of *Jones* and *Singletary*, if such a combination were proper, would disclose taking an *oral decongestant only, 30 minutes before flight*. With respect to claim 1, neither reference, alone or in combination, discloses the combination of ingesting a nasal decongest and applying a decongestant spray into the nose as a preventative measure. In addition, neither reference, alone or in combination, discloses taking the oral decongestant at

least one hour before the scheduled aircraft landing and taking the topical decongestant at a later time during the flight. With respect to claim 13 neither reference, alone or in combination, discloses instructions for taking a combination of medications, an oral decongestant and a topical decongestant, as a preventative measure. In addition, neither reference, alone or in combination, discloses instructions for ingesting an oral decongestant at least one hour before the scheduled aircraft landing time and subsequently spraying a topical decongestant into at least one nostril, within about an hour of the scheduled landing time.

In summary, then, the references as a whole, whether looked at individually or in combination, do not directly or inherently disclose the method of claim 1, "ingesting a nasal decongestant at least one hour before the scheduled aircraft landing time" and "applying a nasal decongestant spray into the nose later in flight than the ingestion of the nasal decongestant." Similarly, the references as a whole, whether considered individually or in combination, do not directly or inherently disclose the kit of claim 13, "instructions for the user to ingest a proper dose of the oral nasal decongestant at least one hour before the scheduled aircraft landing time" and "to subsequently spray the nasal spray decongestant into at least one nostril within about an hour of the scheduled landing time."

Accordingly, combining *Jones* and *Singletary*, even if proper, cannot be read as disclosing all the elements of claims 1 or 13.

D. Conclusion

In conclusion, claims 1 and 13 are patentable over *Jones* and *Singletary* for at least three reasons. First, the Examiner's reasoning for combining the references is improper under the law of 35 U.S.C. § 103. Second, the cited references teach away from the claimed invention, and

thus cannot be used to establish a *prima facie* case of obviousness. Third, even if *Jones* and *Singletary* are combined, the combined references do not disclose all the elements of claims 1 or 13.

Claims 2-12 and 14-20, then, must also be patentable, since "[i]f an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious." M.P.E.P. § 2143.03, *citing*, *In re Fine*, 837 F.3d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988).

For the above reasons, the Appellant respectfully submits that all pending claims comply with the written description requirement and are patentable over the references of record. Allowance is respectfully requested.

Respectfully submitted,

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VIII. APPENDIX OF CLAIMS INVOLVED IN APPEAL

1. A method of relieving the potential for symptoms of ear and sinus cavity blockage in a descending aircraft, comprising:

ingesting a nasal decongestant at least one hour before the scheduled aircraft landing time, for non-specific shrinking of the nasal lining; and

applying a nasal decongestant spray into the nose later in flight than the ingestion of the nasal decongestant, to shrink the nasal lining;

wherein the ingested and sprayed decongestants help to shrink the mucosa, including at least the nasal lining, to decrease the pain associated with blockage as an aircraft descends.

2. The method of claim 1 wherein the ingested nasal decongestant comprises pseudoephedrine.

3. The method of claim 2 wherein the pseudoephedrine dose is about 60 mg.

4. The method of claim 1 wherein the sprayed nasal decongestant comprises phenylephrine.

5. The method of claim 4 wherein the phenylephrine is in up to about a 1% concentration.

6. The method of claim 1 wherein the sprayed nasal decongestant comprises oxymetazoline.

7. The method of claim 6 wherein the oxymetazoline is in up to about a 1% concentration.

8. The method of claim 1 wherein the ingestion step takes place within about six hours of the scheduled aircraft landing time.

9. The method of claim 8 wherein the spray step takes place within about one hour of the scheduled aircraft landing time.

10. A method of relieving the potential for symptoms of ear and sinus cavity blockage in a descending aircraft, comprising:

ingesting about 60 mg of pseudoephedrine at least one hour before the scheduled aircraft landing time, for non-specific shrinking of the nasal lining; and

applying a nasal decongestant spray into the nose after the pseudoephedrine ingestion and within about one hour of scheduled landing time, to shrink the nasal lining;

wherein the ingested and sprayed decongestants help to shrink the mucosa, including at least the nasal lining, to decrease the pain associated with blockage as an aircraft descends.

11. The method of claim 10 wherein the sprayed nasal decongestant comprises phenylephrine.

12. The method of claim 1 wherein the sprayed nasal decongestant comprises oxymetazoline.

13. A kit for use in relieving the potential for symptoms of ear and sinus cavity blockage in descending aircraft, comprising:

a first medication comprising an oral nasal decongestant;

a second medication comprising a nasal spray decongestant; and

instructions for the user to ingest a proper dose of the oral nasal decongestant at least one hour before the scheduled aircraft landing time, and to subsequently spray the nasal spray decongestant into at least one nostril within about one hour of the scheduled landing time;

wherein the ingested and sprayed decongestants help to shrink at least the nasal lining, to decrease pain associated with blockage as the aircraft descends.

14. The kit of claim 13 wherein the ingested nasal decongestant comprises pseudoephedrine.

15. The kit of claim 14 wherein the pseudoephedrine dose is about 60 mg.

16. The kit of claim 13 wherein the sprayed nasal decongestant comprises phenylephrine.

17. The kit of claim 16 wherein the phenylephrine is in up to about a 1% concentration.

18. The kit of claim 13 wherein the sprayed nasal decongestant comprises oxymetazoline.

19. The kit of claim 18 wherein the oxymetazoline is in up to about a 1% concentration.

20. The kit of claim 13 wherein the instructions comprise ingesting the first medication within about six hours of the scheduled aircraft landing time.

IX. EVIDENCE APPENDIX

None.

X. RELATED PROCEEDINGS APPENDIX

None.